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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,844	02/11/2004	Lon J. Wilson	1789-12301	3026
23505	7590	06/14/2007		
CONLEY ROSE, P.C. David A. Rose P. O. BOX 3267 HOUSTON, TX 77253-3267			EXAMINER PERREIRA, MELISSA JEAN	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 06/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/776,844	Applicant(s) WILSON ET AL.	
	Examiner Melissa Perreira	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 11-22 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 23, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/24/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-28 are pending in the application. Claims 11-22 and 24-26 are withdrawn from consideration. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

1. The declaration under 37 CFR 1.132 filed 5/24/07 is sufficient to overcome the rejection of claims 1-3,6,8-10 and 23 based upon the fact that the authorship of the Cubbage et al. reference is identical to the inventorship for the instant application. Therefore the Cubbage et al. reference is not prior art as it is not by others.

Response to Arguments

1. Applicant's arguments with respect to claims 1-8 and 23 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-8,23,27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al. (US 6,123,923) in view of Stahl et al. (US 5,470,843) or Yan et al. (US 5,830,539).

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4. Unger et al. (US 6,123,923) discloses a vesicle composition comprising a stabilizing material, a photoactive agent, bioactive agents and/or targeting ligands and their use for therapeutic applications (column 1, lines 23-33; column 11, lines 47-50). The photoactive agent, fullerene, may be bound to targeting ligands/agents, such as antibodies (column 43, line 49; claim 14) specifically for targeting antigens or for targeting the agent to an area where an immune response is desired (column 47, lines 48-49; column 12, line 40; column 13, lines 60-62; column 14, line 21-22). Stabilizing material, such as phosphorylated or sulfonated lipids may be covalently bound to the photoactive agent to control vesicle size and physical interactions between it and the membranes of a cell or tissue (column 36, lines 40-54; claim 13). The bioactive agents may include antibiotics, such as penicillin. The bioactive agents are intended for therapeutic purposes via administration to a patient and subsequent application of ultrasound (column 64, line 45; column 66, lines 40-46; column 68, lines 5-26). The covalent linking of the stabilizing material and targeting ligands to the photoactive agent are discussed throughout the disclosure (column 55). Unger et al. (US 6,123,923) does not explicitly disclose binding of the antibiotic to the photoactive agent.

5. Stahl et al. (US 5,470,843) discloses a composition comprising a carbohydrate-polymer-linker-potentiator unit. The polymer portion may consist of a fullerene (column 6, line 57) bound to the carbohydrate via a linker (spacer) (column 7, lines 24-25; column 11, lines 39-41) and a potentiator bound to the hydrophobic polymer/fullerene (column 13, lines 1 and 6; column 14, lines 19-23). The polymer/fullerene may also be directly coupled/bound to a drug moiety, such as antibiotics/penicillins, erythromycins,

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etc. (column 14, lines 58+). The role of the potentiator is to improve the affinity of the receptor-binding portion of the molecule or improve the electrostatic interaction of the composition with its cognate receptor and is thus a targeting agent. Also the potentiator improves the overall reactivity of the compound in aqueous solution (column 4, lines 43-52; column 13, lines 6-13 and 20-23). The pharmaceutical compositions/aerosols of the disclosure are suited for the prophylaxis and/or therapy of bacterial and viral infections and of diseases which involve inflammatory processes (column 19, lines 22-27 and 45).

6. Yan et al. (US 5,830,539) discloses the method for coating or functionalizing a substrate, such as a fullerene (column 3, lines 42,46 and 47; column 6, line 31) with a first layer comprising a molecular tether covalently bonded to the surface and a second layer comprising antibiotics bonded to the first layer (abstract; column 3, lines 9-12; column 7, lines 60-63). The fullerene may be further functionalized with targeting ligands, such as antigens, etc. (column 6, lines 45-49).

7. At the time of the invention it would have been obvious to one ordinarily skilled in the art to attach (covalently) antibiotics and antibodies to the photoactive compound (fullerene) of Unger et al. as was done by Stahl et al. or Yan et al. The covalent binding of the antibiotics to the fullerene substrate allows for improved delivery of the antibiotic to the targeted location (i.e. site specificity) in a patient, cells, tissues, etc. via the covalently bound targeting moiety-fullerene compound of Unger et al. The language of claim 8 "wherein the targeting agent is capable of binding to anthrax spores" is not a positive recitation and the agents of the disclosures are also capable of accomplishing the same for example, by attaching antibiotics, such as penicillins or erythromycins to

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the conjugate. The binding of targeting ligands/agents to the fullerene compositions for specific site/receptor targeting is well known in the art as seen in all of the disclosures and would be obvious to include in a fullerene-antibiotic composition. The use of an antigen targeting ligand as seen by Yan et al. ensures targeting to an antigen binding site while the use of phosphorylated or sulfonated lipids as seen by Unger et al. are capable of bone targeting. The inclusion of a potentiator moiety into the fullerene composition improves the solubility of the composition and is advantageous as this increases the binding affinities and results in higher blocking activity than corresponding molecules with lower solubility (Stahl et al., column 5, lines 2-15).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP

June 4, 2007



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER